

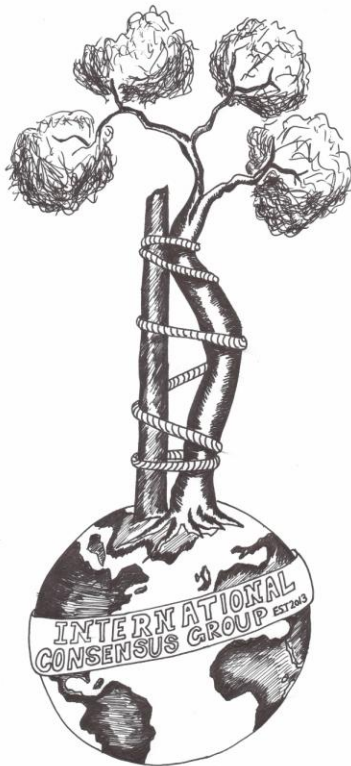
# EXHIBIT C

# **Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection**

Chairmen:

Thorsten Gehrke MD

Javad Parvizi MD, FRCS



**With Immense Gratitude to our Sponsors**

A meeting of this magnitude could not take place without the generous support of industry partners whose mission parallels ours in providing better care for patients. We are indebted to every one of our industry partners for their financial support and more critically for their scholarly input throughout the process. We appreciate their input during the literature review and refinement of questions and their agreement not to be part of the “voting” delegates.

**Platinum Sponsor:**



**Question 1: Do numbers of bacteria arriving in the surgical wound correlate directly with probability of SSI?**

**Consensus:** We recognize that the probability of surgical site infection correlates directly with the quantity of bacteria that reach the wound. Accordingly we support strategies to lower particulate and bacterial counts at surgical wounds.

**Delegate Vote:** Agree: 97%, Disagree: 2%, Abstain: 1% (Strong Consensus)

**Justification:** Postoperative surgical site infections are believed to occur via bacterial inoculation at the time of surgery or as a result of bacterial contamination of the wound via open pathways to the deep tissue layers.<sup>1-3</sup> The probability of surgical site infection is reflected by interaction of parameters that can be categorized into three major groups.<sup>2</sup> The first group consists of factors related to the ability of bacteria to cause infection and include initial inoculation load and genetically determined virulence factors that are required for adherence, reproduction, toxin production and bypassing host defense mechanisms. The second group involves those factors related to the defense capacity of the host including local and systemic defense mechanisms. The last group are environmental determinants of exposure such as size, time and location of the surgical wound that can provide an opportunity for the bacteria to enter the surgical wound, overcome the local defense system, sustain their presence, replicate and initiate local as well as systemic inflammatory reactions of the host.

The use of iodine impregnated skin incise drapes shows decreased skin bacterial counts but no correlation has been established with SSI. However, no recommendations regarding the use of skin barriers can be made (See Workgroup 4 Question 27).

**Question 2: Do numbers of bacteria in the operating room environment correlate directly with the probability of surgical site infection?**

**Consensus:** We recognize that airborne particulate bacteria are a major source of contamination in the operating room environment and that bacteria shed by personnel are the

predominant source of these particles. The focus of our recommendations is to reduce the volume of bacteria in the operating room with particular attention to airborne particles.

**Delegate Vote:** Agree: 93%, Disagree: 5%, Abstain: 2% (Strong Consensus)

**Justification:** Air is a potential source of contamination in the operating room.<sup>2, 4</sup> Studies have demonstrated that the number of airborne bacteria around the wound is correlated to the incidence of PJI.<sup>1</sup> It has been suggested that if it was possible to measure accurately the number of bacteria present in the wound it should constitute the most precise predictor of subsequent infection.<sup>5</sup> Bacteria can be considered as part of the total mass of particulates in the air. Some studies have suggested that the airborne particulate count should be considered as potential surrogate for airborne microbial density.<sup>6</sup> Others have found correlation between the number of particulates larger than 10 micrometers with the density of viable bacteria at the site of surgery (measured by colony forming units).<sup>7</sup> It has been suggested that monitoring particulate count be used as a real-time proxy for increased risk of wound contamination or infection.<sup>7</sup> Persons in the operating room are major source of bacterial load and shed bacterial particulates. These particulates circulate through the operating room via air currents. Movements of objects (personnel and/or operating room equipment including opening and closing doors) can generate significant marked air currents and increase the probability of bacteria being deposited in the surgical site.<sup>3, 8</sup>

**Question 3: Should the operating room (OR) in which an elective arthroplasty is performed be fitted with laminar air flow (LAF)?**

**Consensus:** We believe that arthroplasty surgery may be performed in operating theaters without laminar flow. Laminar flow rooms and other strategies that may reduce particulates in operating rooms would be expected to reduce particulate load. Studies have not shown lower SSI in laminar flow rooms and some cases, are associated with increased rates of SSI. These are complex technologies that must function in strict adherence to maintenance protocols. We do recommend further investigation in this field.

**Delegate Vote:** Agree: 85%, Disagree: 7%, Abstain: 8% (Strong Consensus)